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Re-evaluation Decision RVD2013-01

# Myclobutanil

*(publié aussi en français)*

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## Re-evaluation Decision

After a re-evaluation of the fungicide myclobutanil, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing myclobutanil for sale and use in Canada.

An evaluation of available scientific information found that products containing myclobutanil do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of myclobutanil uses, new mitigation measures must be included on the labels of all products. Additional data are being requested.

The regulatory approach for the re-evaluation of myclobutanil was first presented in Proposed Re-evaluation Decision PRVD2010-14, *Myclobutanil*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of myclobutanil as well as summarizes the Agency's decision and the reasons for it. Comments were received during the consultation process and were taken into consideration. The greenhouse ornamentals risk assessment was updated based on newly submitted data. This resulted in changes in the regulatory decision that was proposed in PRVD2010-14. Appendix I summarizes the comments and provides the PMRA's responses. Appendix III outlines the revised label statements. To comply with this decision, registrants of products containing myclobutanil will be informed of the specific requirements affecting their product registration(s).

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration.[3] The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-14, *Myclobutanil*.

## What Is Myclobutanil?

Myclobutanil is a systemic fungicide with protective and curative action. It is classified as a Resistance Management Mode of Action (MoA) group 3 fungicide and is used to control a number of fungal diseases on a wide variety of plant species. This MoA involves inhibition of fungal ergosterol biosynthesis (steroid demethylation inhibition), which is essential for cell wall formation. The registered uses of myclobutanil belong to the following use site categories: greenhouse food crops, greenhouse non-food crops, terrestrial feed crops, terrestrial food crops, ornamentals outdoor and turf. It is available only in Commercial Class products and is applied by ground application equipment.

## Health Considerations

### Can Approved Uses of Myclobutanil Affect Human Health?

**Additional risk-reduction measures are required on myclobutanil labels. Myclobutanil is unlikely to affect your health when used according to the revised label directions.**

Potential exposure to myclobutanil may occur through diet (food and water) or when handling and applying the product, or through non-occupational exposure at golf courses and pick-your-own operations.

When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using myclobutanil products according to label directions.

An acute overexposure to myclobutanil can produce a variety of symptoms in animals and humans. Symptoms may include ataxia, abdominal breathing, prostration, convulsions, passiveness, salivation, scant droppings, and stained muzzle and anogenital areas. Local effects of an acute dermal exposure may include erythema, edema, and skin sensitization. Contact with the eye may cause vascularization of the cornea, corneal haziness and irritation to both the iris and conjunctiva. To prevent overexposure, label directions must be followed. Additional toxic effects on the liver, testes, kidney, adrenal gland and other organs, as well as effects noted in pregnant females (increased abortions and reduced body weight or body weight gain) and in the fetuses (increased resorptions, reduced viability indices, increased skeletal variations, reduced litter size and reduced fetal weight), were observed in animals at very high doses only; therefore, they would not occur when myclobutanil products are used according to label directions. Based on the weight of evidence, myclobutanil is considered non-carcinogenic. A cancer risk assessment was not required.

Due to the skin sensitizing potential of myclobutanil and increased risk from greenhouse uses, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to myclobutanil. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

**Residues in Water and Food**

**Dietary risks from food and water are not of concern.**

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Dietary exposure to myclobutanil was estimated from residues in treated crops and drinking water for different subpopulations representing different ages, genders and reproductive status. Acute exposure estimates were determined for females 13–49 years old; chronic exposure estimates were determined for all subpopulations including infants and children.

The aggregate acute exposure to myclobutanil from food and drinking water represents 88% of the acute reference dose when using drinking water concentrations generated from water modelling; the aggregate chronic exposure represents 17% of the chronic reference dose for the general population and is in the range of 13% to 51% of the chronic reference dose for all subpopulations, the most exposed subpopulation being all infants less than one year old. Thus, acute and chronic dietary risks are below the level of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk. MRLs are currently established on registered domestic and import agricultural uses and published in Health Canada's List of MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides webpage.

**Triazole metabolites**

Dietary exposure to triazolyl-1-alanine (TA) and triazolyl-1-acetic acid (TAA) may occur from the use of myclobutanil on food commodities. Residues of TA in plant commodities are regulated in Canada not to exceed 2.0 ppm. These metabolites are common to all triazole fungicides, including myclobutanil. The cumulative risks from TA and TAA will be addressed in a separate document.

**Risks in Residential and Other Non-Occupational Environments**

**Non-occupational risks are not of concern.**

There are currently no registered residential uses of myclobutanil, and therefore a risk assessment for this scenario was not required.

An assessment of the potential risk of exposure incurred by the public at "Pick-Your-Own" operations or at public golf courses was conducted. A quantitative analysis was performed for these scenarios to assess whether or not there were risks of concern for the public.

Aggregate exposure estimates were calculated to determine the risk of exposure for the public from all known potential sources: diet, drinking water and non-occupational exposure events such as pick-your-own fruit harvesting or golfing. The combined exposures resulted in margins of exposure (MOEs) greater than the target MOE and are not of concern.

**Occupational Risks from Handling Myclobutanil**

**Occupational mixer/loader/applicator risks are not of concern.**

Based on the precautions and directions for use on the current labels, and based on use information received from the registrant, risk estimates associated with mixing, loading and applying activities did meet current standards and are not of concern. However, in the interest of clarity and consistency, updating the current end use product label language regarding personal protective equipment is required.

**Occupational postapplication risks are not of concern when products are used in accordance with the revised label directions.**

Postapplication occupational risk assessments consider exposures to workers entering treated sites. Most occupational postapplication risks are not of concern if the required protective measures are followed. Based on the precautions and directions for use on the current product labels for registered use scenarios, postapplication risks to workers performing certain activities, such as thinning, pruning and harvesting of certain crops, did not meet current standards and are of concern. However, when the required mitigation measures such as lengthened restricted-entry intervals (REIs) and reduced application frequencies are considered, the risks to postapplication workers are not of concern.

Postapplication exposure is not of concern for golf course workers.

Postapplication exposure is not of concern for greenhouse uses based on the revised risk assessment and revised conditions of use. Appropriate dissipation data were not available for greenhouse uses at the time of the original assessment presented in PRVD2010-14. Following the publication of PRVD2010-14, a greenhouse dislodgeable foliar residue (DFR) study was submitted and reviewed. As a result of the review of this DFR study, the default peak (day 0) DFR value of 3.6% of the application rate and a daily dissipation rate of 3.8% were used in the revised occupational postapplication risk assessment for greenhouse flowers.

In the interest of providing growers with agronomically feasible REIs, the postapplication activities have been divided into four basic categories per crop: Nursery (cut and potted) and Greenhouse (cut and potted). This sub-division is governed by both transfer coefficients and the dissipation rates for each crop. The maximum number of applications for greenhouse cut flowers has been reduced from six per year to four per crop cycle. The maximum number of applications for greenhouse vegetables has been reduced to one per crop cycle. All other applications are as listed on the product labels. In accordance with comments from stakeholders, geraniums and poinsettias are considered to be exclusively greenhouse crops. In order to mitigate worker risk, label changes are required to reflect the resulting restricted-entry intervals. The revised postapplication risk estimates for the greenhouse uses of myclobutanil can be found in Appendix II, and revised label changes can be found in Appendix III.

## Environmental Considerations

**What Happens When Myclobutanil is Introduced into the Environment?**

**Myclobutanil poses a potential risk to birds, small wild mammals and aquatic organisms; therefore, additional risk reduction measures are required.**

When myclobutanil is released into the environment some of it can be found in soil and surface water. Myclobutanil is very persistent, somewhat mobile in soil and very soluble in water and can therefore leach into groundwater and enter surface water in runoff. Myclobutanil residues are not expected in the air because of its low volatility. Myclobutanil has a low potential for bioaccumulation in biota.

Myclobutanil may pose a risk to birds and small wild mammals and to aquatic organisms. Small wild mammals and birds may be at chronic risk on the site of application due to consumption of contaminated food items, and the risk cannot be mitigated. In order to minimize the potential exposure to aquatic organisms, strips of land between the agricultural field and the aquatic areas (buffer zones) will be left unsprayed. The width of these buffer zones will be specified on the product label.

## Value Considerations

**What is the Value of Myclobutanil?**

**Myclobutanil provides good control of a number of diseases on several greenhouse vegetables, field and orchard crops, nursery and greenhouse ornamentals, and golf course turf.**

Myclobutanil is registered in Canada to control a number of fungal diseases including powdery mildew, rust and scab on several greenhouse vegetables, field and orchard crops, as well as nursery and greenhouse-grown ornamental plants and golf course turf grass. Important uses of myclobutanil include foliar treatments to control apple scab, powdery mildew, cedar apple rust and quince rust on apples; black rot and powdery mildew on grapes; powdery mildew on greenhouse vegetables; and brown and summer patch, stem rust, grey snow mold and dollar spot on golf course turf grass. Myclobutanil is also important for the treatment of several foliar diseases, particularly powdery mildew on ornamental crops which need good disease management so as to ensure the production of high quality plants. The ornamental and greenhouse vegetable industries typically lack effective alternatives to myclobutanil.

**Myclobutanil is an important tool for resistance management in an integrated pest management program.**

Myclobutanil has been identified as having a medium level of risk for pathogens to develop resistance to it. It is effective as a systemic fungicide with protective and curative (eradicant) action. Due to these properties, myclobutanil is not only an important tool for disease

management but also is important for resistance management in an integrated pest management program where it is used as a rotational fungicide or as a tank-mix partner with other fungicides belonging to different MoA groups for the same use. Thus, myclobutanil helps to delay the development of resistance by pathogens to other fungicides. It is important in resistance management of diseases for most crops particularly for the management of powdery mildew on greenhouse vegetables and ornamental crops.

## Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Risk-reduction measures are required to address potential risks identified in this assessment. These measures, in addition to those already identified on existing myclobutanil product labels, are designed to further protect human health and the environment. The following additional key risk-reduction measures are required:

**Additional Key Risk-Reduction Measures**

**Human Health**

- Consistent label requirements for personal protection equipment to protect workers mixing, loading and applying myclobutanil.
- Reduced application frequencies and increased restricted-entry intervals to protect workers entering treated sites.
- Ornamental uses are to be sub-divided in four categories: Nursery (cut and potted) and Greenhouse (cut and potted) commodities.
- Restricted application frequency for greenhouse (cut) flowers and greenhouse vegetables.
- In keeping with the use information supplied by the registrant regarding golf course uses: the reduction of application rate to 0.73 kg a.i./ha; reduced application frequencies; reduced application volumes and a restriction to ground-boom only.

**Environment**

- Changes to label statements, including precautionary statements and buffer zones for non-target aquatic habitats are required as a result of the environmental risk assessment.

To reduce the potential of myclobutanil to run off to adjacent aquatic habitats and for contamination of groundwater, advisory statements are required.

## What Additional Scientific Information is Being Requested?

Additional environmental data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter.

### Environment

The following data requirements are needed to support the continued registration of myclobutanil and to refine buffer zones for estuarine/marine aquatic habitats.

| | |
|---|---|
| DACO 9.4.5: | Chronic toxicity to estuarine/marine invertebrates |
| DACO 9.5.2.4: | Acute and chronic toxicity to estuarine/marine fish |

## Other Information

Any person may file a notice of objection[5] regarding this decision on myclobutanil within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

5 As per subsection 35(1) of the *Pest Control Products Act*.

# Appendix I Comments and Responses

## 1.0 Comments Pertaining to Value

### 1.1 Comment on the value of myclobutanil in the greenhouse vegetable sector

The Canadian greenhouse vegetable sector believes it is critical to continue to have access to myclobutanil, which is a key active ingredient for integrated disease management of powdery mildew and gummy stem blight on cucumbers; Botrytis blight and powdery mildew on tomatoes; and powdery mildew on peppers in greenhouses. Due to the significant impact of powdery mildew on greenhouse vegetable production, growers have identified it as one of the top national disease priorities for all three crops. The Canadian greenhouse vegetable sector also believes the loss of this control option would make it almost impossible to successfully manage powdery mildew and other diseases on greenhouse vegetables.

The availability and viability of chemical pest management practices for the registered site and pest combinations is limited.

**PMRA Response:**
The PMRA acknowledges that myclobutanil is an important fungicide for integrated disease management on greenhouse cucumbers, tomatoes and peppers particularly under a rapidly developing powdery mildew infestation and high disease pressure situations. The PMRA also agrees that, although there are some registered alternatives to myclobutanil, most of them are registered for disease suppression only or permit fewer applications per crop cycle. Furthermore, myclobutanil is the only MoA group 3 fungicide with both protective and curative modes of action that is registered for the control of powdery mildew and gummy stem blight on cucumbers; Botrytis blight and powdery mildew on tomatoes; and powdery mildew on peppers grown in greenhouses. These properties make myclobutanil an important tool for resistance management when used in rotation with other fungicides from other MoA groups.

### 1.2 Comment on the value of myclobutanil in the greenhouse ornamental sector

The loss of myclobutanil on greenhouse ornamental crops would constitute a significant loss of a critical industry tool for the control of powdery mildew and rusts. At present, myclobutanil is the only active ingredient available that is considered to be an eradicant and its loss would leave growers extremely vulnerable to disease outbreak and spread. The loss of myclobutanil to cut flower producers would be an even greater concern that will have severe implications because of the long term nature of their crops. The available alternatives to myclobutanil for the control of powdery mildew for ornamental flowers are copper, dodemorph-acetate, potassium bicarbonate and the biofungicides, *Streptomyces lydicus* strain WYEC 108 and the QST 713 strain of dried *Bacillus subtilis*. Of these, dodemorph-acetate is registered only on field and greenhouse mini potted roses. All other products are registered for suppression only and work solely based on contact. Another disease that is of concern in chrysanthemum is white rust (*Puccinia horiana*) which is listed by the Canadian Food Inspection Agency (CFIA), the United States Department of Agriculture (USDA) and the Animal Plant Health Inspection Service (APHIS) as a serious quarantinable pest. The CFIA has recognized only myclobutanil as an eradicant in their

protocols. As Canadian growers have experienced limited outbreaks of *P. horiana*, and given that outbreaks in Eastern USA border states have recently been reported, not having any registered products to control this disease is alarming.

**PMRA Response:**
The PMRA agrees that, because of the systemic translocation, and protective and curative properties of myclobutanil, it is a very important tool for the management of foliar fungal diseases particularly, powdery mildew and rust on greenhouse potted and cut flower ornamentals. Due to its curative property, growers can apply myclobutanil even after the initial infestation has already started which makes it a flexible tool for disease management compared to registered alternatives. The PMRA acknowledges that the number of registered alternatives for the control of powdery mildew is limited, none is as efficacious as myclobuatnil, and they have limitations regarding the number of applications permitted per crop cycle. The PMRA also agrees that reduced risk fungicides such as biofungicides generally do not have disease control properties equivalent to myclobutanil and cannot be used as an eradicant.

Based on the revised occupational postapplication risk assessment, myclobutanil can continue to be used used as an eradicant on chrysanthemum white rust (*Puccinia horiana*) for greenhouse and nursery chrysanthemum, which is listed by the CFIA as being a disease of quarantine significance in Canada. Due to this property, myclobutanil, along with other control measures, may help as a component of the eradication protocol needed to salvage asymptomatic plants from infected nursery stock.

## 2.0 Comments Pertaining to the Health Risk Assessments

### 2.1 Comments on the Occupational Exposure Risk Assessment

#### 2.1.1 Comment on the use of the dissipation default of 0% in the assessment of greenhouse flowers

The use of the dissipation default of 0% dissipation/day in the risk assessment of greenhouse flowers is an overly conservative value, especially relative to the approach of the United States Environmental Protection Agency.

**PMRA Response:**
In 2012, the study *Determination of Dissipation and Dislodgeability of Greenhouse-Applied Pesticide (Myclobutanil) and the Potential Chronic Exposures of Workers in Ornamental Greenhouse Plants* (PMRA# 2248940) was submitted to the PMRA by Flowers Canada to address this concern. The PMRA has reviewed the submitted study and revised the postapplication risk assessment for greenhouse flowers based on the study results.

Dislodgeable foliar residue (DFR) data are used to assess the potential exposure to workers from plant foliage when re-entering fields or greenhouses that have been treated with pesticides. These data measure the residue level and the rate of residue decline over time.

The DFR data requirements to support a registration as well as the evaluation methods used by Health Canada are consistent with other regulatory agencies such as the United States Environmental Protection Agency. This level of consistency is being supported by on-going initiatives such as joint reviews and work shares at the North American Free Trade Agreement and Organisation for Economic Co-operation and Development levels.

Chemical-specific DFR data are used by Health Canada and other regulatory agencies to more accurately predict potential exposure and risk. Where such data do not exist, science based assumptions are used to estimate the dislodgeable residues (i.e. the residue level and the rate of decline).

The study was designed to estimate dislodgeable foliar residues after two applications of myclobutanil on greenhouse chrysanthemums. The DFR data listed in the study report was not used in the linear regression analysis since the field samples had been corrected for the recoveries from the field fortification samples. Since the field fortification recoveries were within the acceptable range and all were above 95%, it was not required to correct the field samples for field recoveries. The uncorrected raw data was used for the linear regression analysis. The equation of the line from the linear regression analysis was deemed acceptable with an $R^2$ value of 0.9821. The predicted peak DFR value from the linear regression analysis was calculated as 0.539 $\mu g/cm^2$, which is lower than the actual field sample taken four hours after the second application – 0.593 $\mu g/cm^2$.

A revised risk assessment was conducted using the initial residue value of 3.6% and a daily dissipation rate of 3.8% (as determined by the PMRA study review) in order to determine a new restricted-entry interval (REI) for greenhouse cut flowers. The results of the revised calculations are presented in Tables 1.1–1.3 of Appendix I; target MOEs for greenhouse cut flowers cannot be achieved within an agronomically feasible REI beyond four applications per crop cycle. Therefore, end-use product labels will recommend a maximum of four applications, 10 days apart, per growing cycle.

### 2.1.2 Comment on the transfer coefficient defaults used for the risk assessment of greenhouse flowers

A comment was received regarding the apparent use of elevated transfer coefficient (TC) defaults (4000 $cm^2/hr$) for regulatory decisions relating to crops other than cut flowers. On page 66 of PRVD2010-14, Table 2 refers to greenhouse roses (cut and potted), gerbera, aster, chrysanthemums and geraniums and lists the transfer coefficient as 4000 $cm^2/hr$. Among the listed crops, all are commonly grown as potted ornamental plants (similar to poinsettias) and therefore the accepted TC of 400 $cm^2/hr$ should be used in the risk assessment.

**PMRA Response:**
The TC of 4000 $cm^2/hr$ is used by the PMRA in postapplication risk assessments for cut flowers. The transfer coefficient of 400 $cm^2/hr$ is used by the PMRA in postapplication risk assessments for potted ornamentals, including flowers. These values are based on accepted studies supplied by the Agricultural Re-Entry Task Force (ARTF, 2008). Since cut flower workers are expected to perform harvesting activities in a variety of flowers, a TC of 4000 $cm^2/hr$ is considered appropriate for estimating risk. Since the current labels do not specify whether the crops listed are potted or cut flowers, the TC of 4000 $cm^2/hr$ must be applied to all greenhouse flower crops

treated with myclobutanil, in order to be protective of the relatively high exposure activities involved in the production of cut flowers.

With the possible exception of poinsettias, which are marketed almost exclusively as potted ornamentals, all greenhouse flower crops listed on the myclobutanil labels are marketed as cut flowers in addition to being grown as potted ornamentals. Since the current labels do not specify whether the crops listed are potted or cut flowers, the PMRA has conducted a revised occupational postapplication risk assessment to include separate label statements adapted to differentiate between cut and potted flowers.

Consequently, the PMRA has applied both the 4000 $cm^2$/hr and the 400 $cm^2$/hr TC to all greenhouse flower crops in a revised postapplication risk assessment (See Appendix II, Tables 1.1 and 1.2). The resulting REIs (Appendix II , Table 2.0) must be added to end use product labels accordingly, which should be amended to differentiate between cut and potted flowers.

In addition, the revised postapplication risk assessment clearly differentiates between nursery and greenhouse crops, although the division is not clear on all current product labels. Nursery crops were assessed using a default 10% daily dissipation rate, and the greenhouse flowers have been evaluated using a default daily dissipation rate of 3.8%. The resulting REIs can be added to product labels provided that the registrant and growers are agreeable to separate label instructions for:

- greenhouse cut flowers;
- greenhouse potted flowers;
- nursery cut flowers and
- nursery potted flowers.

As a potential mitigation measure, reduced applications were considered for all greenhouse and nursery crops with REIs that are potentially agronomically unfeasible. Tables 1.1 to 1.3 of Appendix II detail the results of the revised risk assessment.

### 2.1.3 Comment on the greenhouse risk assessment

The greenhouse risk assessment is overly conservative, and the widespread use of personal protective wear by workers in greenhouse operations should considerably mitigate any risk of worker exposure to residues post application.

**PMRA Response:**
The data and science-based assumptions used to calculate exposure in the myclobutanil risk assessment are in keeping with the current practices of the PMRA and are recognized as a suitable regulatory standard. In the absence of pertinent data, conservative assumptions are necessary in order to be protective of any potential risks of concern. At present, there is insufficient data to estimate the rate of pesticide residue decline in a greenhouse setting. Therefore, the default assumptions in the risk assessment of the use of myclobutanil on greenhouse vegetables must be retained. Following the publication of PRVD2010-14, a greenhouse flowers DFR study has been submitted; values derived from this study were applied in the revised risk assessment in Appendix II.

### 2.1.4 Comment on the number of applications used for greenhouse vegetables

The label of the product currently registered for use on greenhouse vegetables indicates that it can be used 6 times per year on greenhouse cucumbers, 2 times per year on greenhouse tomatoes and 3 times per crop cycle on greenhouse peppers. Even with these application frequencies, growers still struggle to control powdery mildew and gummy stem blight, and therefore the loss of this control option will make it almost impossible to successfully manage these diseases.

**PMRA Response:**
In the document PRVD 2010-14, the Re-evaluation of Myclobutanil, the PMRA detailed the use pattern used in the risk assessments for mixer/loader/applicators and postapplication workers. The risk assessment was conducted using the following application parameters:

Greenhouse cucumbers: 6 applications, 14 days apart, at a rate of 0.136 kilograms of active ingredient per hectare (kg a.i./ha).
Greenhouse tomatoes: 2 applications, 7 days apart, at a rate of 0.136 kg a.i./ha.
Greenhouse peppers: 3 applications, 12 days apart at a rate of 0.136 kg a.i./ha.

The risk assessment was conducted in accordance with the current practices described by stakeholders and sufficient to address pest pressures

# Appendix II Revised Postapplication Risk Estimates for the Greenhouse Uses of Myclobutanil

## Table 1.1 Ornamental Intermediate-Term Postapplication Exposure Estimates

| Crop | Applications Per Year or Cycle | | Rates [c] (kg a.i./ha) | Activity | Transfer Coefficient [d] ($cm^2$/hr) | DFR [e] (µg/$cm^2$) at REI | Dermal Exposure [f] (µg/kg bw/day) | MOE [g] | REI [h] (days) |
|---|---|---|---|---|---|---|---|---|---|
| | Number [a] | Interval [b] (days) | | | | | | | |
| Greenhouse (potted): roses, gerbera, aster, chrysanthemums, geraniums | 6 | 10 | 0.136 | all | 400 | 0.14 | 3.14 | 795 | 0.5 |
| Greenhouse (cut): roses, gerbera, aster, chrysanthemums, geraniums | 6 | 10 | 0.136 | all | 4000 | 0.10 | 23.97 | 104 | 7 |
| Greenhouse (potted) poinsettias | 6 | 10 | 0.112 | all | 400 | 0.11 | 2.59 | 966 | 0.5 |
| | | | | | | | | | |
| Nursery (potted): roses, gerbera, aster, chrysanthemums | 6 | 10 | 0.136 | all | 400 | 0.42 | 9.53 | 262 | 0.5 |
| Nursery (cut): roses, gerbera, aster, chrysanthemums | 6 | 10 | 0.136 | all | 4000 | 0.12 | 26.91 | 93 | 12 |

[a] The label listed number of applications per year (nursery) or per cycle (greenhouse).
[b] The minimum listed label application interval described in days.
[c] Maximum listed label rates expressed in kilograms a.i./hectare.
[d] Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document (Revised - August 7, 2000) and any amendments thereof (PMRA 2008).
[e] Based on DFR data (see PRVD 2010-14), at x days after application, where x is the day when an MOE ≥100 is determined or the proposed REI. A default peak (day 0) DFR value of 20% of the application rate and the default daily dissipation rate of 10% for nursery crops were used. For greenhouse flowers, a peak (day 0) DFR value of 3.6% of the application rate and the daily dissipation rates of 3.8% were used based on submitted DFR data (PMRA# 22489490).
[f] Dermal exposure = DFR x TC × 8 hr × DA / 70 kg.
[g] The resulting MOE on the recommended REI day. Based on the intermediate-term dermal NOAEL of 2.5 mg/kg/day and a dermal target MOE of 100. Shaded cells indicate those calculated MOEs that failed to meet the target MOE of 100.
[h] Day at which the dermal exposure results in an MOE ≥100 or the minimum REI of 12 hours as per current labels (See PRVD 2010-14 for details). All REIs are set following the final application.

## Table 1.2 Ornamental Intermediate-Term Postapplication Exposure Estimates with Reduced Applications

| Crop | Applications per Cycle | | Rates [b] (kg a.i./ha) | Activity | Transfer Coefficient [c] ($cm^2$/hr) | DFR [d] ($\mu g/cm^2$) at REI | Dermal Exposure [e] ($\mu g$/kg bw/day) | MOE [f] | REI [g] (days) |
|---|---|---|---|---|---|---|---|---|---|
| | Number [a] | Interval [b] (days) | | | | | | | |
| Greenhouse (cut): roses, gerbera, aster, chrysanthemums, geraniums | 4 | 10 | 0.136 | all | 4000 | 0.12 | 26.40 | 95 | 1 |

[a] The number of applications for these greenhouse crops has been reduced to 4 for the purposes of risk mitigation.
[b] Maximum listed label rates expressed in kilograms a.i./hectare.
[c] Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document (Revised - August 7, 2000) and any amendments thereof (PMRA 2008).
[d] Based on DFR data (see Section PRVD 2010-14), at 0 days after application. For greenhouse cut flowers, a peak (day 0) DFR value of 3.6% of the application rate and the daily dissipation rates of 3.8% were used based on submitted DFR data (PMRA# 22489490).
[e] Dermal exposure = DFR x TC x 8 hr x DA / 70 kg.
[f] The resulting MOE on the recommended REI day. Based on the intermediate-term dermal NOAEL of 2.5 mg/kg/day and a dermal target MOE of 100. Shaded cells indicate those calculated MOEs that failed to meet the target MOE of 100.
[g] The minimum REI of 24 hours as per current labels (See PRVD 2010-14 for details). All REIs are set following the final application.

## Table 1.3 Greenhouse Vegetable Intermediate-Term Postapplication Exposure Estimates with Single Applications

| Crop | Applications per Cycle [a] | Rates [b] (kg a.i./ha) | Activity | Transfer Coefficient [c] ($cm^2$/hr) | DFR [d] ($\mu g/cm^2$) at REI | Dermal Exposure [e] ($\mu g$/kg bw/day) | MOE [f] | REI [g] (days) |
|---|---|---|---|---|---|---|---|---|
| Greenhouse peppers, tomatoes, cucumbers | 1 | 0.136 | all | 1800 | 0.27 | 27.98 | 89 | 0.5 |

[a] The number of applications for these greenhouse crops has been reduced to one for the purposes of risk mitigation.
[b] Maximum listed label rates expressed in kilograms a.i./hectare.
[c] Transfer coefficients are from the Science Advisory Council for Exposure Agricultural Transfer Coefficient document (Revised - August 7, 2000) and any amendments thereof (PMRA 2008).
[d] Based on DFR data (see Section PRVD 2010-14), at 0 days after application. A default peak (day 0) DFR value of 20% of the application rate was used.
[e] Dermal exposure = DFR x TC x 8 hr x DA / 70 kg.
[f] The resulting MOE on the recommended REI day. The REI has been set to day 0 based on the current labels and grower practices. Based on the intermediate-term dermal NOAEL of 2.5 mg/kg/day and a dermal target MOE of 100. Shaded cells indicate those calculated MOEs that failed to meet the target MOE of 100.
[g] The minimum REI of 12 hours as per current labels (See PRVD 2010-14 for details). All REIs are set following the final application.

# Appendix III Revised Label Amendments for Products Containing Myclobutanil

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements given below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

**Application Rates**

All labels must be changed to specify a maximum application rate for golf course turf of 7.3 grams per 100 square meters (0.73 kg a.i./ha ) and a maximum area treated per day of 8 hectares.

**Soluble Granules in Water Soluble Packaging (WSP)**

All myclobutanil products currently formulated as soluble granules must be in water soluble packaging. The following label instructions should be added to clearly indicate directions for water soluble packaging:

> Product "X" is a soluble granule sealed within a water soluble bag. **DO NOT** open or puncture water soluble bag for any reason. **DO NOT** use opened or punctured water soluble bag for any reason. If broken water soluble bags are found when container is opened, avoid contact with, and inhalation of the product. Wear chemical resistant coveralls, chemical resistant gloves and a respirator to dispose of broken water soluble bags according to **DISPOSAL** section.

**Ornamentals**

The label of the commercial end-use product Nova 40W Agricultural Fungicide (Registration Number 22399) must be amended to include the following use directions.

- Ornamental uses are to be sub-divided in four categories: Nursery (cut and potted) and Greenhouse (cut and potted) commodities.
- Reduced applications on greenhouse (cut) flowers.

**Application Intervals**

All labels must be changed to specify: "Limit the number of applications to a maximum of (value from Table 1) with a minimum of (value from Table 1) days between applications."

**Table 1 Application Intervals**

| Crop | Applications per Year | |
|---|---|---|
| | Number | Interval (days) |
| apples | 6 | 7 |
| cherries (sweet & sour), peaches, nectarines | 6 | 7 |
| asparagus (post-harvest) | 5 | 7 |
| grapes | 5 | 14 |
| strawberries | 6 | 14 |
| Saskatoon berries | 3 | 14 |
| carnations | 6 | 10 |
| Outdoor ornamental trees & shrubs: pear (flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering), azalea/rhododendron, honeysuckle, lilac | 6 | 14 |
| Outdoor ornamental trees & shrubs: crab-apple (flowering); nursery crops: ash, amelanchier | 6 | 10 |
| outdoor ornamental roses | 4 | 10 |
| outdoor ornamental juniper | 4 | 14 |
| Outdoor ornamental flowers, shrubs: iris, roses, hollyhock, phlox, | 6 | 10 |
| Greenhouse (potted) poinsettias | 6 | 10 |
| Greenhouse (potted): rose, gerbera, ester, chrysanthemums, geraniums | 6 | 10 |
| Greenhouse peppers, cucumbers, tomatoes | 1[1] | - |
| Greenhouse (cut): rose, gerbera, ester, chrysanthemums, geraniums | 4[1] | 10 |
| Nursery (cut and potted): roses, gerbera, aster, chrysanthemums | 6 | 10 |
| Turf (Kentucky bluegrass grown for seed) | 2 | 14 |
| Turf (golf courses) | 2 | 14 |

[1]Maximum number of applications per crop cycle

**Maximum Spray Volume**

Where maximum spray volume is not currently specified the following statement should be added:

> Apply at the recommended rate using a maximum spray volume of 1000L per hectare, unless otherwise stated.

**Use Precautions**

To reduce bystander exposure, the following statements must be added to all labels:

> Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.
>
> Keep the following personal protective equipment immediately available for use in case of emergency (i.e., a broken package, spill, or equipment breakdown): chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant foot wear, chemical-resistant head gear and a respirator.
>
> Hazardous to humans and domestic animals. Keep out of reach of children.
>
> Causes eye irritation. A potential skin sensitizer. May cause irritation to the nose, throat and skin. Harmful if swallowed, inhaled, or absorbed through the skin. **DO NOT** get in eyes, on skin or breathe spray mist.
>
> **DO NOT** apply by air.
>
> Use only properly calibrated groundboom, chemigation or hand held equipment as specified by the label.
>
> Use only properly calibrated groundboom equipment for turf applications.
>
> Not for use by homeowners or other uncertified users.
>
> **DO NOT** use in residential areas (excepting golf courses). Residential areas are defined as sites where bystanders including children may be potentially exposed during or after spraying. This includes around homes, school, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.

**Personal Protective Equipment**

For consistency between labels, and for the purpose mitigating the risk of exposure to myclobutanil, the following directions must be included on all labels:

> Wear goggles, mid-forearm to elbow-length chemical- resistant gloves, chemical-resistant footwear, a wide brimmed hat, chemical-resistant coveralls over long pants and a long-sleeved shirt and an appropriate respirator when mixing, loading, and applying this product. Pants or coveralls should be worn outside footwear to prevent pooling within boots.
>
> Remove protective equipment immediately after handling this product. Wash outside of gloves and footwear before removing. As soon as possible, wash thoroughly and change into clean clothing. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this products concentrate. **DO NOT** reuse them. Contaminated clothing must be laundered separately in hot water before reusing. Wash hands and face thoroughly after handling and before eating, drinking, chewing gum, smoking, or using toilet.
>
> **DO NOT** enter treated areas for a minimum of 12 hours for all crops (unless a longer REI is specified) or until sprays have dried for golf courses. Wear gloves, long sleeved shirts, long pants, a hat and work boots when entering treated areas, including greenhouses, for harvesting, pruning, thinning, suckering or for any other agricultural practice in the treated area. **DO NOT** apply this product in such a manner as to directly, or through drift, expose workers or other persons. Unprotected persons must be vacated from the area being treated. Only protected handlers may be in the area during application.

**Restricted-Entry Intervals**

Where deemed necessary, restricted-entry intervals (REIs) are subdivided according to re-entry activities. Any REI calculated to be less than 24 hours will be listed as 0.5 days (or until the spray has dried for golf courses) in order to be consistent with current label recommendations.

These restricted-entry intervals must be added to the appropriate labels as listed below:

**Table 2 Restricted-Entry Intervals**

| Crop | Activity | REI[a] (days) |
|---|---|---|
| apples, cherries (sweet & sour), peaches, nectarines | thinning | 12 |
| | hand harvest | 5 |
| | hand pruning, scouting, pinching, tying, training, hand weeding, propping, animal control, mechanical harvest (cherries only) | 0.5 |
| asparagus | All | 2 |
| grapes | cane turning and girdling | 14 |
| | hand harvesting & pruning, training, thinning, tying, leaf pulling | 7 |
| | hand line irrigation, scouting, hand weeding | 0.5 |
| strawberries | hand harvest, pinching, pruning, training | 2 |
| | irrigation, mulching, scouting, hand weeding | 0.5 |
| Saskatoon berries | hand harvest, hand pruning, hand thinning | 3 |
| | scouting, hedging, irrigating, hand weeding | 0.5 |
| carnations | all | 17 |
| Outdoor ornamental trees & shrubs: pear (flowering), crab apple,(flowering), privet, dogwood, euonymus, hawthorn, juniper (flowering & non-flowering), honeysuckle, lilac, crab-apple (flowering); nursery crops: ash, amelanchier | all | 0.5 |
| Outdoor ornamental roses | all | 11 |
| Outdoor ornamental flowers, shrubs: iris, roses, hollyhock, phlox | all | 12 |
| Kentucky bluegrass grown for seed | harvesting/transplanting treated turf, mowing, watering, irrigation, aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding | 0.5 |
| Golf course turf | transplanting treated turf | 12 |
| | mowing, watering, irrigation, aerating, fertilizing, hand pruning, repair, mechanical weeding, scouting, seeding, cup changing, grooming | dried spray |
| Greenhouse (potted) roses, gerbera, aster, chrysanthemums, geraniums, poinsettias | All | 0.5 |
| Greenhouse (cut) roses, gerbera, aster, chrysanthemums, geraniums, | All | 1 |
| Greenhouse peppers, tomatoes, cucumbers | All | 0.5 |
| Nursery (potted) roses, gerbera, aster, chrysanthemums, | All | 0.5 |
| Nursery (cut) roses, gerbera, aster, chrysanthemums, | All | 12 |

[a] Day at which the dermal exposure results in an MOE ≥100 or the minimum label REI of 1 or 0.5 days (or until spray has dried for golf courses).

**ENVIRONMENTAL HAZARDS**

All environmental statements under "**PRECAUTIONS**" and "**ENVIRONMENTAL HAZARDS**" on the labels for NOVA 40W (registration number 22399) and EAGLE WSP fungicides (registration number 26585) should be replaced by the following statements, under the following sections:

Add to **ENVIRONMENTAL HAZARDS**

**TOXIC** to birds and small wild mammals.

**TOXIC** to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE.**

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable ( for example, sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Add to **DIRECTIONS FOR USE**

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

**DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

**DO NOT** apply by air.

**Buffer zones:**

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

| Method of application | Crop | | Buffer Zones (metres) Required for the Protection of: | | | | |
|---|---|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | | Terrestrial habitat |
| | | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m | |
| Field sprayer | Turfgrass (golf courses), carnations, grapes, asparagus, azalea, dogwood, euonymus, honeysuckle, lilac, privet, hawthorn, juniper, pear | | 1 | 0 | 1 | 1 | 1 |
| Airblast | Grapes | Early growth stage | 2 | 0 | 1 | 0 | 1 |
| | | Late growth stage | 1 | 0 | 1 | 0 | 1 |
| | Cherries, hollyhock, crabapple, nursery ornamentals, rose, peaches, apples, azalea, dogwood, euonymus, honeysuckle, lilac, privet, hawthorn, juniper, pear, Saskatoon berries | Early growth stage | 4 | 0 | 2 | 0 | 2 |
| | | Late growth stage | 2 | 0 | 1 | 0 | 1 |

# Appendix IV Additional Data Requirements

The following studies or suitable scientific rationale are required as a condition of continued registration under section 12 of the *Pest Control Products Act.*

**Data Requirements Related to the Environmental Assessment**

The following data requirements are needed to support the continued registration of Myclobutanil and to refine buffer zones for estuarine/marine aquatic habitats.

| | |
|---|---|
| DACO 9.4.5: | Chronic toxicity to estuarine/marine invertebrates |
| DACO 9.5.2.4: | Acute and chronic toxicity to estuarine/marine fish |

# References

## Additional Studies and Information Considered for the re-evaluation of myclobutanil

### A. Published Information


| PMRA Document Number | Reference |
|---|---|
| 2285316 | Brouwer, R, DB, Brouwer, S, Tigssen, and J.J. van Hemmen, 1992. Pesticides in the Cultivation of Carnations in Greenhouses: Part II - Relationship Between Foliar Residues and Exposures, Am. Ind. Assoc. I. 53(9):582-587 (1992). DACO: 5.6 |
| 2285321 | California Environmental Protection Agency, 2002. Pesticide Exposure of Workers in Greenhouses. Health & Safety Report HS-1835. November 19, 2002. DACO: 5.6 |


### B. Unpublished Information


| PMRA Document Number | Reference |
|---|---|
| 1599342 | Schipper, H.I., Brouwer, D.H. and van Hemmen, J.J., 1998. Exposure to Pesticides During Re-entry Activities in Greenhouses. Field Study in Cucumber Crop. October 6, 1998. INO Nutrition and Food Research Institute, Netherlands Organisation for Applied Scientific Research. DACO: 5.6 |
| 2061780 | Flowers Canada Growers, 2011. Email from C. Gates to Christian Bart : 'Re: Myclobutanil re -evaluation : comments on PRVD 2010-14'. Flowers Canada Growers, 45 Speedvale Ave, Unit 7, Guelph, May 30th, 2011. DACO: 5.2 |
| 2115788 | Agricultural Reentry Task Force (ARTF). 2008. Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. DACO: 5.9 |
| 2248940 | Bestari, K., 2012. 'Determination of Dissipation and Dislodgeability of Greenhouse-Applied Pesticide (Myclobutanil) and the Potential Chronic Exposures of Workers in Ornamental Greenhouse Plants'. Flowers Canada Growers, 45 Speedvale Ave, Unit 7, Guelph, Ontario. November 7th, 2012. |